PSJ3

Exhibit 561A

Cardinal Health, Inc. v. Holder

Attachment 12
to
Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction

SETTLEMENT AND RELEASE AGREEMENT
AND
ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Appendix A to this Agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all Cardinal DEA registered facilities identified in Appendix A.

BACKGROUND

1. Cardinal is registered with DEA at 27 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" of "the Act"). See Appendix A.

2. On November 28, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 801 C Street NW, Suite B, Auburn, Washington 98001 ("Auburn Facility"). See Appendix B.

3. On December 5, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 2045 Interstate Drive, Lakeland, Florida 33805 ("Lakeland Facility"). See Appendix C.

4. On December 7, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 1120 Commerce Boulevard, Swedesboro, New Jersey 08085 ("Swedesboro Facility"). See Appendix D.

5. On January 30, 2008, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause to Cardinal, with respect to its distribution facility located at 13651 Dublin Court, Stafford, Texas 77477 ("Stafford Facility"). See Appendix E.

6. The Orders to Show Cause referenced above alleged, among other things, that Cardinal failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal.

7. DEA also alleges that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located at the following addresses:

a. 500 Jerry Steele Lane, McDonough, Georgia 30253 ("McDonough Facility").

b. 27680 Avenue Mentry, Valencia, California 91355 ("Valencia Facility").

c. 4875 Florence Street, Denver, Colorado 80238 ("Denver Facility").

8. DEA alleges that Cardinal failed to report suspicious orders of controlled substances as more fully set forth in Appendix F, Paragraph 8 as required by 21 C.F.R. § 1301.74(b) .

9. The Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances.

STIPULATION AND AGREEMENT

The facts alleged in the Orders to Show Cause and the facts alleged in paragraphs 7 and 8 above as otherwise summarized above, if proven at an administrative hearing, could constitute grounds for revoking the DEA registrations of the facilities referenced in paragraphs 2-5 and 7 above. In lieu of continuing proceedings to revoke the DEA registrations for the facilities referenced in paragraphs 2-5 and 7 above, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, all outstanding administrative claims and/or issues with respect to the alleged failure of Cardinal to detect and report suspicious orders and the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, including but not limited to the conduct described in the Orders to Show Cause, and all outstanding claims and or issues with respect to the allegations set forth in paragraphs 7 and 8 above. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Cardinal of liability or of the veracity of any allegation made by DEA in the Orders to Show Cause, this Agreement or any investigation, nor a concession by DEA that its allegations in the Orders to Show Cause and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. the conduct alleged in the Orders to Show Cause (Appendices B-E);

b. the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, at all distribution facilities listed in Appendix A operated, owned, or controlled by it;

c. the conduct described in Appendix F, Paragraph 8 to this Agreement; and

d. the alleged failure of Cardinal to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before September 30, 2008.

II. Terms and Conditions

1. Obligations of Cardinal.

a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

b. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). Cardinal shall begin transmitting this information for all controlled substances no later than 90 days after the Parties have mutually agreed upon a format and as soon as practicable

for carisoprodol and tramadol. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

c. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within thirty days of the Effective Date of this Agreement that Cardinal will no longer be required to provide suspicious order reports or any other type of report regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty days written notice.

d. Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement and the Settlement Agreement at Appendix F, whichever is later.

e. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

f. Cardinal agrees that within 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Cardinal's compliance program.

g. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the

rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

h. Cardinal agrees to pay to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) the amount of $34,000,000.00 in settlement of claims or potential claims for civil penalties made by the United States of America for failing to report suspicious orders of controlled substances. Payment of said amounts shall be made by Cardinal in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix F, Paragraph 13. Cardinal agrees to execute the Settlement Agreement at Appendix F simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said amounts within 30 days of the Effective Date of this Agreement.

i. Any material breach by any Cardinal facility of subsections II(1)(a)-(h) of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

a. At Cardinal's request, DEA shall provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members and Cardinal employees at Cardinal trade shows, or at Cardinal internal training sessions, and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II(1)(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

c. Within 150 days of the Effective Date of this Agreement, but not earlier than the later of 90 days after the Effective Date of this Agreement, or 30 days after the previously suspended distribution center re-commences distribution of controlled substances, DEA shall conduct reviews of the functionality of Cardinal's diversion compliance program ("Compliance Reviews") at up to seven Cardinal

distribution centers, consisting of the Auburn Facility; the Lakeland Facility; the Stafford Facility; the Swedesboro facility; and two other Cardinal distribution centers selected by DEA, as well as the Controlled Substance Anti-Diversion investigatory files and processes maintained at Cardinal's Dublin, Ohio headquarters. DEA shall also review the investigatory files maintained by Cardinal of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify Cardinal no less than 48 hours prior to commencing a Compliance Review at a distribution center or at Cardinal's Dublin, Ohio headquarters. DEA shall issue a Notice of Inspection to Cardinal upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, Cardinal shall provide DEA with information in a form reasonably agreed to related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate Cardinal representative to provide DEA's preliminary conclusions regarding the Compliance Review. The parties agree that, at Cardinal's option, Cardinal may be represented by counsel at such Compliance Reviews and that DEA shall neither object to nor limit the number of counsel present at such Compliance Reviews.

d. The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to Cardinal on or before 165 days from the Effective Date of Agreement, stating that Cardinal failed to meet any of the requirements in either subsections II(2)(d)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with Cardinal within 48 hours regarding such a finding. DEA shall consider remedial measures that Cardinal has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

e. DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix F.

f. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA

shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

g. DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to September 30, 2008, which may allege that Cardinal failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by Cardinal to DEA on or before September 30, 2008, for indications that Cardinal may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix F, Paragraph 8) occurring before September 30, 2008, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

h. DEA represents that upon execution of this Agreement, Cardinal's pending application for renewals of the controlled substance registrations of the Auburn, Swedesboro, Lakeland, and Stafford facilities will be granted.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Auburn, Lakeland, Swedesboro, and Stafford facilities.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders to Show Cause and this Agreement; and

b. Refrain from filing any administrative claims against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of September 30, 2008, and the review of the reports and records Cardinal submitted to DEA prior to September 30, 2008.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further,

nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Cardinal's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than

those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to paragraphs II(2)(c) and (d) of this Agreement to Cardinal shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Mark Hartman, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614 757 6597; email: mark.hartman@cardinalhealth.com;
b. With copy to: Steve Falk, General Counsel – HSCS, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614 757 5051; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

Kerry Clark
Chairman and Chief Executive Officer

Dated:

Ivan Fong
Chief Legal Officer and Secretary

Dated:

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated:

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated: 9/26/08

FOR Wendy H. Goggin
Chief Counsel

Dated: 10/2/08

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

Dated: 9/30/2008

Ivan K. Fong
Chief Legal Officer and Secretary

Dated: Sept. 30, 2008

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated: 09-30-08

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated: 9/30/08

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated:

Wendy H. Goggin
Chief Counsel

Dated:

APPENDIX A

APPENDIX A

(Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (Specialty Pharmaceutical).

5. 2512 West Cott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 500 Jerry Steele Lane, McDonough, Georgia, operating under DEA registration number RC0271267.

7. 14601 County Road 212, Findlay, Ohio, operating under DEA registration number RC0313940.

8. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

9. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

10. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

11. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (Specialty Pharmaceutical).

12. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

13. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

14. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

15. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

16. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

17. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

18. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

19. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

20. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

21. 4 Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

22. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW0263056.

23. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

24. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

25. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

26. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

27. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (Parmed Pharmaceuticals).

APPENDIX B

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

NOV 28 2007

IN THE MATTER OF

Cardinal Health
801 C Street NW, Suite B
Auburn, Washington 98001

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RW0191813, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0191813 is assigned to Cardinal Health's Auburn, Washington, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on January 28, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0191813 at 801 C Street NW, Suite B, Auburn, Washington 98001. DEA number RW0191813 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

a. Respondent's largest purchaser of combination hydrocodone products in 2007, Horen's Drugstore, Inc. ("Horen's Drugstore"), is a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical

purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

b. Despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies such as Horen's Drugstore, and despite the public information readily available to Respondent regarding Horen's Drugstore's association with rogue Internet pharmacy websites, Respondent repeatedly supplied Horen's Drugstore with excessive amounts of hydrocodone. Specifically, Respondent distributed in excess of 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007; including over 116,000 dosage units in July; over 129,000 dosage units in August; and over 122,000 dosage units in September.

c. Respondent, disregarding the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances, distributed unusually large amounts of hydrocodone to Horen's Drugstore. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0191813 is hereby suspended, effective December 3, 2007, at 12:00 p.m. Pacific Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for January 28, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 11/28/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date _____ Time _____ Diversion Investigator _____

APPENDIX C

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator

Washington, D.C. 20537

DEC 05 2007

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RC0182080, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RC0182080 is assigned to Cardinal Health's Lakeland, Florida, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 9, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA number RC0182080 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From August 2005 through October 2007, Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

3. Many of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

a. Retail pharmacies in Florida order an average of less than 8,400 dosage units of hydrocodone per month. Respondent distributed hydrocodone to pharmacies engaged in the diversion of controlled substances as reflected in the chart below. Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.

Pharmacy	Total Dosage Units	Number of Months Distributions Made	Monthly Average	Dates of Distribution (*Distributions not made in every month)
Medipharm-Rx, Inc.	620,030	4	155,007	Aug – Dec 05*
DRM Enterprises, Inc.	929,600	22	42,254	Jan 06 – Oct 07
Jen-Mar Pharmacy Services, Inc.	353,700	11	32,154 1st 3 mos: 2,766 Last 8 mos: 43,175	Mar 06 – Feb 07*
Armenia Pharmacy, Inc.	132,900	12	11,075 1st 6 mos: 1,900 Last 6 mos: 20,250	Mar 06 – Feb 07
National Pharmacy, Inc.	659,800	9	73,311	Aug 05 – May 06*
Parulmed Corporation	468,400	20	23,420	Aug 05 – Apr 07*
Q-R-G, Inc.	1,213,200	5	242,640	Feb – June 06
RKR Holdings, Inc.	741,000	13	57,000	Aug 05 – Jan 07*
United Prescription Services, Inc.	1,148,100	4	287,025	Jul – Oct 06
Satellite Drug and Pharmacy	1,044,000	19	54,947 1st 4 mos: 375 Last 15 mos: 69,500	Feb 06 – Oct 07*

b. Respondent distributed hydrocodone to the pharmacies identified in subparagraph 3.a, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from the

Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

c. Respondent distributed hydrocodone to each of the pharmacies named in subparagraph 3.a, above, and to other pharmacies engaged in Internet diversion schemes, in amounts that far exceeded the legitimate needs of its customers.

d. On September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for the Respondent, sent an email to DEA's E-Commerce Section stating that the Respondent had discontinued its sales of controlled substances to 13 suspected Internet pharmacies. Included in Respondent's report of discontinued accounts was the aforementioned RKR Holdings, Inc. ("RKR"). On that same date, Respondent distributed 200 dosage units of combination hydrocodone products to RKR. From September 1, 2006, to January 31, 2007, Respondent distributed 393,600 dosage units of combination hydrocodone products to RKR.

4. Respondent repeatedly supplied the pharmacies named in paragraph 3.a, above, and other pharmacies, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers' association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective December 10, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 9, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/5/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date _____ Time _____ Diversion Investigator _____

APPENDIX D

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

IN THE MATTER OF

DEC 0 7 2007

Cardinal Health
1120 Commerce Blvd.
Swedesboro, NJ 08085

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0269654, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0269654 is assigned to Cardinal Health's Swedesboro, New Jersey, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 7, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

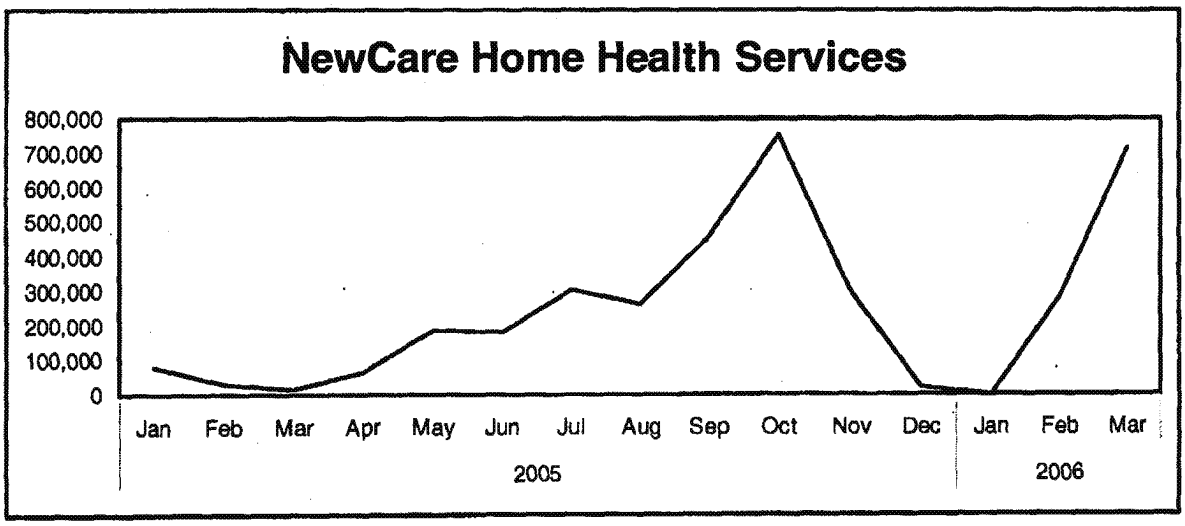
1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0269654 at 1120 Commerce Blvd., Swedesboro, New Jersey 08085. DEA number RW0269654 will expire on May 31, 2008.

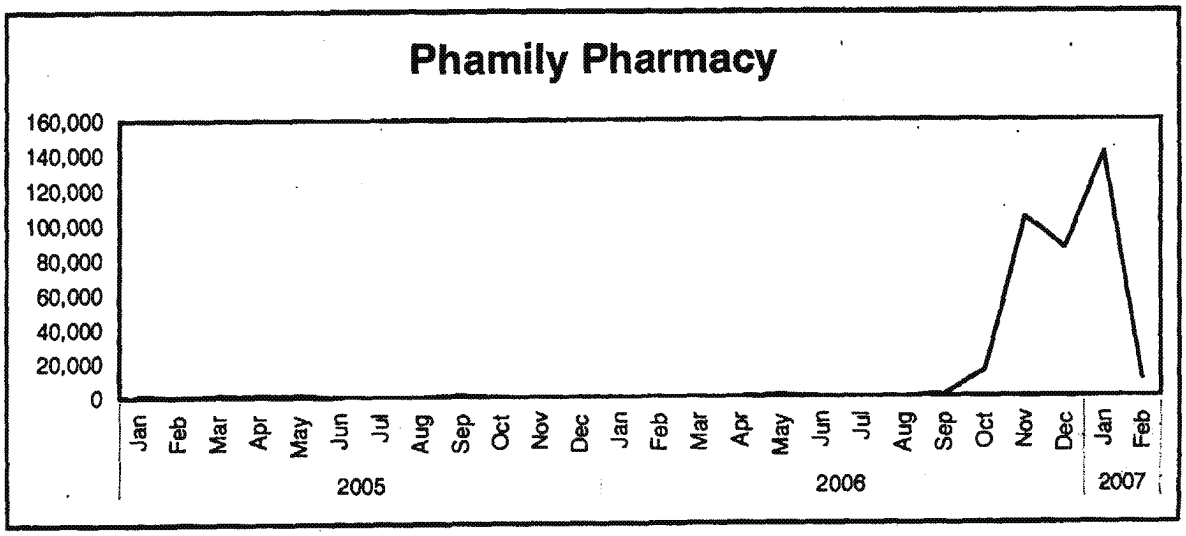
2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From January, 2005 through August, 2007, Respondent distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

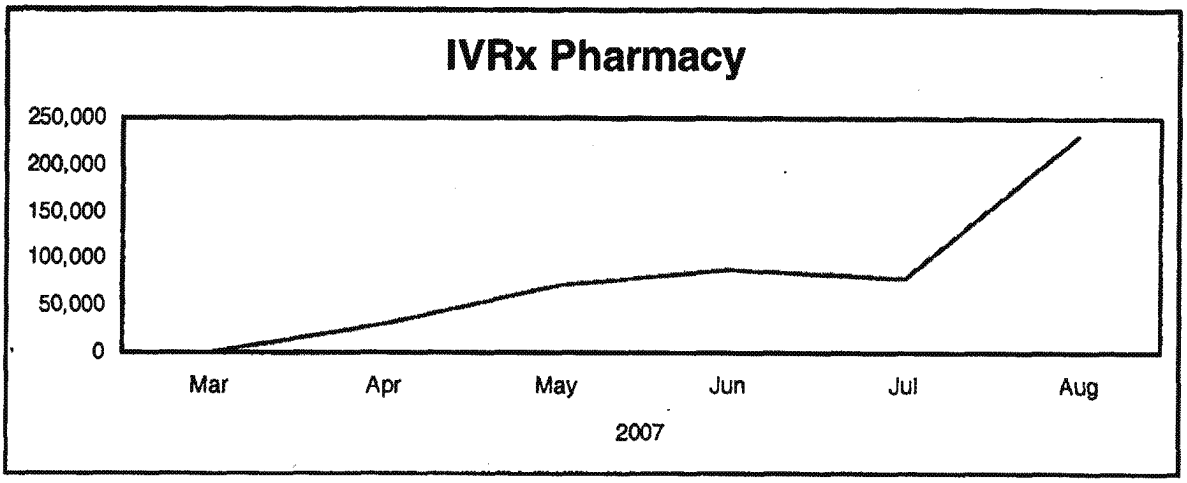
3. Some of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported

prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from drug distribution websites, in violation of applicable Federal and State law. *See United Prescription Services, Inc.*, 72 Fed. Reg. 50,397 (2007).

4. Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled substances, i.e., NewCare Home Health Services, Phamily Pharmacy and IVRx Pharmacy. Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels. The following graphs reflect the total dosage units of hydrocodone combination products that Respondent distributed to each pharmacy.







5. Respondent distributed hydrocodone to the pharmacies identified in paragraph 4, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

6. Respondent repeatedly supplied the pharmacies named in paragraph 4, above, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding the pharmacies' association with drug distribution websites, and despite the suspicious nature of the orders placed by these pharmacies. *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0269654 is hereby suspended, effective December 13, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 7, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's position on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/7/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX E

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JAN 3 0 2008

IN THE MATTER OF

Cardinal Health
13651 Dublin Court
Stafford, Texas 77477

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Cardinal Health ("Registrant") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, at a place and time to be determined, (if Registrant requests such a hearing), as to why DEA should not revoke DEA Certificate of Registration, RC0333524, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Registrant's continued registration is inconsistent with the public interest. DEA Certificate of Registration RC0333524 is assigned to Cardinal Health's Stafford, Texas Distribution Center. The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts.

1. Registrant is registered with DEA as a distributor in Schedules II-V under DEA number RC0333524 at 13651 Dublin Court, Stafford, Texas 77477. DEA number RC0333524 will expire on May 31, 2008.

2. Registrant distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substance – Registrant did not have sufficient policies and procedures in place to detect and prevent diversion; did not execute those policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.

3. Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances.

4. Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.

5. The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

6. Despite Registrant's policy limiting a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units a day, Registrant frequently distributed hydrocodone in quantities that greatly exceeded this limit. Registrant, however, rarely scrutinized these purchases, and in the few instances where Registrant investigated a particular order, it was frequently done by employees with little or no training in the prevention and detection of diversion and/or by employees with a direct financial interest in the successful completion of the transaction.

7. From January 2, 2007 through September 11, 2007, Registrant distributed approximately 1,381,500 dosage units of hydrocodone to Richmond Pharmacy, or approximately 160,000 dosage units each month. During that period, Registrant distributed hydrocodone to Richmond on 142 days. On each of those days, Richmond's purchase of hydrocodone exceeded the daily limit set by Registrant for its retail pharmacy customers. More recently, on each of the eight days in September in which Registrant shipped hydrocodone to Richmond, Richmond grossly exceeded Registrant's threshold of hydrocodone distributions without scrutiny by Registrant's employees. Registrant distributed 66,000 dosage units of hydrocodone to Richmond on September 4, 2007; 6,000 dosage units on September 5, 2007; 12,000 dosage units on September 6, 2007; 18,000 dosage units on September 7, 2007; 48,000 dosage units on September 10, 2007; 24,000 dosage units on September 11, 2007; and 12,000 dosage units on September 12, 2007. Additionally, on September 17, 2007, Registrant shipped 12,000 dosage units of hydrocodone to Richmond, despite having been notified on September 14, 2007, that Richmond surrendered its DEA registration on September 13, 2007, and was no longer authorized to order or dispense controlled substances.

8. Registrant likewise failed to scrutinize the ordering practices of other retail pharmacy customers who exceeded their monthly limit of hydrocodone purchases and other controlled substances, and continued to distribute massive amounts of controlled substances to these customers despite the fact that these customers routinely exceeded, by huge margins, their monthly limit for purchases of particular controlled substances.

THE following procedures are available to Registrant in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause Registrant may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Registrant fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Registrant may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Registrant's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Registrant decline to file a request for a hearing or, should Registrant request a hearing and then fail to appear at the designated hearing, Registrant shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk
Office of Administrative Law Judges